

DEPARTMENT OF THE AIR FORCE 59TH MEDICAL WING (AETC) JOINT BASE SAN ANTONIO - LACKLAND TEXAS

8 APR 2016

MEMORANDUM FOR SGOZ

ATTN: CAPT BRYANT J WEBBER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

- Your paper, entitled <u>The Impact of Chagas Disease on Military Training in Texas</u> presented at <u>Military Health System Research Symposium Website</u> with MDWI 41-108, and has been assigned local file #<u>16134.</u>
- 2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
- 3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
- 4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS									
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7. FUNDING RECEIVED FOR THIS STUDY?									
8. DO YOU NEED FUNDING SUPPORT FOR P	PUBLICATION PURPOSE	S: [YES NO						
9. IS THIS MATERIAL CLASSIFIED? YES									
10. IS THIS MATERIAL SUBJECT TO ANY LEGAND DEVELOPMENT AGREEMENT (CRADA), YES NO NOTE: If the answer is YES	MATERIAL TRANSFER	AGREE	MENT (MTA), INTELLE	CTUAL PROPER	RTY RIGHTS	AGREEMENT ETC.?			
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13. 59 MDW PRIMARY POINT OF CONTACT	14. DUTY	. DUTY PHONE/PAGER NUMBER							
Webber, Bryant J. (bryant.webber@us.af.n				671-4087	571-4087				
15. AUTHORSHIP AND CO-AUTHOR(S) List in				rior ovalend		TI TI ON 10			
a. Primary/Corresponding Author	GRADE/RANK	5	QUADRON/GROUP/OF	FICE SYMBOL	INSTI	TUTION (If not 59 MDW)			
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b. Pawlak, Mary T.	O-3	559	THLS/ 559 MDG/ SC	GOZ					
c. Valtier, Sandra	GS-13	59 N	IDW/ST/CAMD						
d. Daniels, Candelaria C.	0-4				US Ar	my Public Health Com			
e. Cropper, Thomas L.	GS-14	559	THLS/ 559 MDG/ S	GOZ					
f. Tully, Charla C.	0-4				DIMO				
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Prevalence and Seroprevalance of *Trypanosoma cruzi* among U.S. Military Members in South Texas

Bryant J. Webber, MD, MPH*; Mary T. Pawlak, MD, MPH*; Sandra Valtier, PhD*; Thomas L. Cropper, DVM, MPVM, DACVPM*; Sallie L. Hall*; Candelaria C. Daniels, PhD**; Charla C. Tully, DO***

- *59th Medical Wing, Joint Base San Antonio Lackland, Texas
- **U.S. Army Public Health Command South, Joint Base San Antonio Fort Sam Houston, Texas
- ***Defense Institute for Medical Operations, Joint Base San Antonio Lackland, Texas

Background

An estimated 300 thousand U.S. residents are infected with *Trypanosoma cruzi*, the causative parasitic agent of Chagas disease. Although the majority of cases are in Latin American immigrants, evidence points to increasing incidence of autochthonous cases of Chagas disease. In its first year, this study reported the prevalence and seroprevawelence of Chagas disease among military members who may be at increased risk due to field training activities conducted around the San Antonio area, where *T. cruzi*-infected triatomines have been identified.

Methods

U.S. Air Force basic training field instructors, students graduating from security forces training, and military working dog instructors volunteered to have blood drawn and answer a questionnaire regarding risk factors for Chagas disease. Real-time polymerase chain reaction (PCR) and two serologic tests (enzyme-linked immunosorbent assay (ELISA) for IgG and IgM and immunofluorescence assay (IFA) for IgG) were conducted on blood samples. Descriptive statistics were used to analyze the prevalence and seroprevalence of *T. cruzi* and risk factors.

Results

A total of 416 individuals were enrolled in 2015. Of the tests conducted (PCR [N=403]; ELISA [N=408]; IFA [N=408]), all were negative for *T. cruzi*. The participants reported a total of 3,038 (mean = 7) weeks spent in a triatomine-endemic field environment, 113,661 (mean = 273) weeks living or traveling in Southwest U.S. and Latin America, and 6,189 (mean = 15) weeks camping or hunting in Southwest U.S. and Latin America.

Conclusions

To date, this study demonstrates that Chagas disease is not a significant risk to military members conducting field training in south Texas. Study enrollment will continue with funding for 3,000 participants.

Disclosures

This project is funded by the Air Force Medical Support Agency (award # D-14-009). The views expressed are those of the authors and do not reflect the official views or policy of the Department of Defense or its Components. The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40.402.



59th Medical Wing (59th MDW) Institutional Review Board (IRB)

59 Clinical Research Division/SGVUS 2200 Bergquist Dr, Bldg 4430, Lackland AFB, TX 78236-9908 Federal Wide Assurance #FWA00001750 and DoD Assurance #50007

NOTICE OF ACTION REGARDING IRB REVIEW

Date: 6 May 2015

TO: Capt Bryant Webber, SGOZ

Protocol Number: FWH20140074H (402055)

Title: The Impact of Chagas Disease on Military Training in Texas (#402055-1)

Your Continuing Review 'Progress Report' submitted on 10 Apr 2015 for the protocol named above was Approved by the convened IRB on 28 Apr 2015. The Board determination is provided below:

Documents Reviewed: Progress Report, Literature Review, ICD stamped, Form A-1 Principal Investigator's Multi-Purpose Signature Sheet

IRB determinations:

The study risks continue to be minimized and reasonable in relation to the potential benefits, if any to subjects, and the importance of the knowledge that may reasonably be expected to result. Selection of subjects continues to be equitable. The plan continues to adequately monitor data for subject safety and to have adequate provisions for subject privacy and confidentiality. Informed consent will continue to be sought from each prospective subject and appropriately documented.

It was noted that the PI, 2 Al's, 1 RA, 3 RC's completed an approved investigator training program. No untrained investigator's were listed. The Board determined that only the investigator's listed below were approved for this study (all other previously listed investigators will be dropped from the study):

- Bryant Webber, PI (training expires 12/06/16)
- Dr. Sandra Valtier, AI (training expires 01/15/16)
- Capt Mary Pawlak, AI (training expires 08/18/17)
- David Hill, RA (training expires 09/30/17)
- Michele Tavish, RC (training expires 07/31/17)
- Lois Robinson, RC (training expires 10/10/17)
- Constance Kowat, RC (training expires 10/30/15)

The Board determined no changes were required for the study.

The Board determined external monitoring of the study was not necessary. The Board agreed that the Principal Investigator's designation of the **Medical Utilization** category of the Surgeon General's Community Health Project should remain unchanged.

The Board voted to approve this Progress Report as written and determined that it remains not readiness related. The minimal risk study was approved for one year. The new expiration date is 27 May 2016 (based on this study's existing expiration date, which, the IRB will use as a fixed anniversary date, if IRB approval occurred within 30 days of expiration. The study will be reviewed in approximately 11 months for continuing review. The next progress report is due 12 Apr 2016 (See attached table). FOLLOW-UP: CLOSED

If you have requested funds, you should contact the CRD Resource Manager at (2-7924) as to the status of requested funds. YOU ARE NOT AUTHORIZED TO USE YOUR SECTION'S O&M FUNDS.

Name of Official
MARIA DOMINGUEZ

Signature DOMINGUEZ.MARIA.E.

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DEPARTMENT OF THE AIR FORCE 59TH MEDICAL WING (AETC) JOINT BASE SAN ANTONIO - LACKLAND TEXAS

IRB MEETING	24 Nov 15	No Dec IRB	26 Jan 16	23 Feb 16	22 Mar 16	26 Apr 16	24 May 16	28 Jun 16	26 Jul 16	23 Aug 16	27 Sep 16	25 Oct 16	22 Nov 16	No Dec IRB
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Report reports line	13 Oct 15	13 Oct 15	10 Nov 15	12 Jan 16	9 Feb 16	8 Mar 16	12 Apr 16	10 May 16	14 Jun 16	12 Jul 16	9 Aug 16	13 Sep 16	11 Oct 16	11 Oct 16
Progress Report And other reports Deadline	turn in by	turn in by	turn in by	turn in by	turn in by	turn in by	turn in by	turn in by	turn in by	turn in by	turn in by	turn in by	turn in by	turn in by
Progress Reports For studies expiring between	25 November – 25 December	26 December – 26 January	27 January – 23 February	24 February – 22 March	23 March – 26 April	27 April – 24 May	25 May – 28 June	29 June – 26 July	27 July - 23 August	24 August – 27 September	28 September – 25 October	26 October - 22 November	23 November – 26 December	27 December - 24 January
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Deadline for New Protocol Submission (By 1600 hours, 4 th Monday previous month)	26 Oct 2015		23 Nov 2015	25 Jan 2016	22 Feb 2016	28 Mar 2016	25 Apr 2016	23 May 2016	27 Jun 2016	25 Jul 2016	22 Aug 2016	26 Sep 2016	24 Oct 2016	